REMARKS

This amendment is presented in response to the Office Action mailed February 9, 2005. Claims 11 and 31 are amended. For the reasons stated below, Applicant requests favorable reconsideration and allowance of all claims in the application.

Hilton Davis / Festo Statement

The amendments herein were not made for any reason related to patentability. Claim 11 is amended to give it greater clarity. Claim 31 is amended to supply an omitted word. The foregoing amendments are not related to the pending rejections; all amendments were made for reasons other than patentability.

35 USC 102: Claims 1-3, 6, 8, 14, 18-19, 25-29, 32-37

1. Claims 1-3, 6, 8, 14, 18-19, 25-29, 32-3 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,971,983 ("Lesh"). The current rejection is defective because the applied reference does not teach the features of the claims, as required by law.

The examiner bears the burden of establishing a *prima facie* case of anticipation. *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138-139 (Fed. Cir. 1986). The prior art reference must disclose each element of the claimed invention, as correctly interpreted, and as arranged in the claim. *Lindemann Maschinefabrik Gmbh v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. MPEP § 2131.

Claim 1

Claim 1 is patentable over Lesh because Lesh fails to teach the combination:

A method for treating a dilatation of a body, including the steps of:

inserting a catheter into a localized region of said body;

exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region;

allowing said substance to perfuse into a tissue of said localized region;

emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance; and

contracting said dilatation;

whereby at least some tissue in said localized region is treated.

At the outset, claim 1 is patentable over Lesh because Lesh does not describe a method for treating a dilatation of a body. Lesh is directed to a tissue ablation device for creating linear lesions in the wall of a body space of an animal, particularly a specific portion of the left atrial wall (Abstract, line 1 to line 3), the left atrium being a portion of the heart. As opposed to a dilatation, such as an aneurysm, which is an abnormal condition indicative of pathology, it is well known that the presence of a heart in an animal or human is an entirely normal phenomenon. Nor is there any suggestion in Lesh that the relevant portion of the heart is abnormally dilated. Thus, there is no teaching in Lesh of treating a dilatation.

Claim 1 is further patentable over Lesh because Lesh fails to teach:

"contracting said dilatation;

whereby at least some tissue in said localized region is treated."

As defined by Lesh, "ablation" is the "substantial altering of the mechanical, electrical, chemical, or other structural nature of the tissue. In the context of intracardiac ablation applications as shown and described with reference to the embodiments below, 'ablation' is intended to mean sufficient altering of the tissue properties to substantially block conduction of electrical signals from or through the ablated cardiac tissue . . ."(Col. 9, line 29 to line 36). It has already been established that Lesh has nothing to do with treatment of dilatations. Accordingly, Lesh is directed to a device that partially destroys the conductive system of the heart.

Figs. 10a and 10f of Lesh depict an embodiment that includes an ablation element equipped with a plurality of suction ports. The function of said suction ports is to anchor the ablation element against the atrial wall such that the ablation element is firmly in contact with the atrial wall during the ablation. As shown in Figure 10f, the ablation element is highly flexible, thus allowing it to conform to the surface contour of the atrial wall. Lesh also suggests that the treatment element may be formed with a bias to the tissue contours to enhance contact between the treatment element and the atrial wall (Col. 21, line 14 to line 17. In each of Figs. 3-9 and 20 the treatment element is shown in close contact with the atrial wall, conforming to the contours of the wall. Thus, while Lesh applies suction to the atrial wall, such application of suction is done in order to conform the shape of the treatment element to the atrial wall's contours and to anchor it to the atrial wall, not to contract the atrial wall. Accordingly, Lesh fails to teach contracting a dilatation.

Additionally, even if Lesh could be said to teach contracting of the tissue, such contracting would be only temporary, in order to enhance contact between the tissue and the treatment element. There is, accordingly, no teaching in Lesh of "contracting said dilatation; whereby at least some tissue in said localized region is treated."

The Examiner has failed to point to any specific teachings from Lesh that anticipate the elements of claim 1. Accordingly, she has failed to establish *prima facie* anticipation. On these facts alone, there is no anticipation of claim 1 by Lesh. Additionally, because Lesh fails to teach each and every element of claim 1, as required by law, there is no anticipation of claim 1 by Lesh. Accordingly, claim 1 is patentable over Lesh.

Claim 3

Claim 3 is patentable over Lesh because Lesh fails to teach "wherein said localized region includes cancerous, engorged, inflamed or infected tissue." As above, Lesh is directed to ablation of the atrial wall. Because Lesh fails to teach "wherein said localized region includes cancerous, engorged, inflamed or infected tissue . . . ," even if claim 1 were not patentable over Lesh, claim 3 would be patentable over Lesh.

Claim 6

Claim 6 is patentable over Lesh because Lesh fails to teach "wherein said localized region is associated with a body system, said body system including a blood vessel, lung tube, lung pocket, gastrointestinal system, urogenital system, nerve or nerve sheath." As above, Lesh is directed to ablation of the atrial wall. Because Lesh fails to teach "wherein said localized region is associated with a body system, said body system including a blood vessel, lung tube, lung pocket, gastrointestinal system, urogenital system, nerve or nerve sheath . . . ," even if claim 1 were not patentable over Lesh, claim 6 would be patentable over Lesh.

Claim 18

Claim 18 is patentable over Lesh because Lesh fails to teach "wherein said treatment includes shrinkage of said lumen or said sphincter to a selected dimension." As above, Lesh is directed to ablation of the atrial wall. Because

Lesh fails to teach "wherein said treatment includes shrinkage of said lumen or said sphincter to a selected dimension . . . ," even if claim 1 were not patentable over Lesh, claim 18 is patentable over Lesh.

Claim 19

Claim 19 is patentable over Lesh because Lesh fails to teach "wherein said treatment includes shrinkage of said lumen or said sphincter to a substantially normal dimension." As above, Lesh is directed to ablation of the atrial wall. Because Lesh fails to teach "wherein said treatment includes shrinkage of said lumen or said sphincter to a substantially normal dimension . . . ," even if claim 1 were not patentable over Lesh, claim 19 would be patentable over Lesh.

Remaining Dependent Claims

Even without considering any individual merits of the remaining dependent claims, these claims are distinguished from Lesh because they depend from independent claims that are distinguished as discussed above. *Cf.* If an independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

2. Claims 1-3, 6, 8, 14, 18-19, 25-29, 32-37stand rejected under 35 USC § 102(e) as being anticipated by U.S. Patent Pub. No. 2004/0097901 ("Whalen"). The current rejection is defective because the applied reference does not teach the features of the claims, as required by law.

Claim 1: Whalen fails to teach the following combination:

A method for treating a dilatation of a body, including the steps of:

inserting a catheter into a localized region of said body;

exuding from said catheter a substance capable of perfusing into at least

some tissue in said localized region;

allowing said substance to perfuse into a tissue of said localized region;

emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance; and

contracting said dilatation;

whereby at least some tissue in said localized region is treated.

Claim 1 is patentable over Whalen because Whalen fails to teach:

"exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region . . . ." There is no teaching or suggestion whatsoever in Whalen of exuding a substance capable of perfusing into tissue in a localized region. Whalen describes a method of embolizing vascular sites wherein an embolizing composition is delivered to the vascular site. The reference describes an embolizing composition as including a biocompatible polymer, a biocompatible co-polymer and a biocompatible solvent (paras. 0094 to 0101). There is no mention that the embolizing composition has the characteristic of being able to perfuse into the tissue. In fact, Whalen describes biocompatible polymers as being "insoluble in blood or other bodily fluid . . ." (para. 0025). Thus, because of its immiscibility in blood and other bodily fluids, it is highly unlikely that it is capable of perfusing into tissue. Furthermore, because the object of Whalen is to embolize, *i.e.* fill, the vascular site, the choice of a composition that perfused into the tissue would undermine the primary object of Whalen's invention, filling in the vascular site. Accordingly, Whalen fails to teach "exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region . . . ."

Claim 1 is further patentable over Whalen because Whalen fails to teach:

"allowing said substance to perfuse into a tissue of said localized region . . . " As shown in Whalen's Fig. 10, the embolizing composition is delivered to a vascular site such as an aneurysm, which forms a void. The embolizing

composition is injected into the site until a nidus forms within the aneurysm (para 0145). Thus, the result of injecting the embolizing composition is the formation of a structure within the aneurysm, rather than perfusion of the composition into the tissue. Accordingly, Whalen fails to teach "allowing said substance to perfuse into a tissue of said localized region . . . . "

Claim 1 is further patentable over Whalen because Whalen fails to teach:

"emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance . . . ." None of the apparatus of Figs. 1-10 of Whalen includes any element or elements with which energy emitted into the embolizing composition delivered into the aneurysm. Nor is there any teaching to the effect. As described in para. 0122, the composition is briefly heated prior to being delivered into the catheter. There is no further application of thermal energy to the composition. In fact, para. 0123 emphasizes that it is rapid delivery of the composition to the vascular site that allows it to maintain its temperature. Accordingly, Whalen fails to teach "emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance . . . ."

Claim 1 is further patentable over Whalen because Whalen fails to teach:

"contracting said dilatation . . . . " Whalen is directed to a method of *embolizing* vascular sites. It is well known to those having an ordinary level of skill that embolization is obstruction of the vascular site by placement of a material mass in the vascular site. As practiced in Whalen, a mass of embolizing composition is delivered to the aneurysm and allowed to cure, presumably by cross-linking. As described in paras. 145 to 151 of Whalen, the embolizing composition is delivered to the aneurysm until it is filled in. There is no teaching or suggestion whatsoever that the embolizing composition has any effect on the tissue itself, such as causing the tissue to contract. The role of the embolizing composition is to fill the void created by the aneurysm. Thus, there is no

teaching or suggestion in Whalen of "contracting said dilatation . . . . " The Examiner has failed to point to any specific teachings from Whalen that anticipate the elements of claim 1. Accordingly, she has failed to establish *prima facie* anticipation. On these facts alone, there is no anticipation of claim 1 by Whalen. Additionally, because Whalen fails to teach each and every element of claim 1, as required by law, there is no anticipation of claim 1 by Whalen. Accordingly, claim 1 is patentable over Whalen.

Claim 3

Claim 3 is patentable over Whalen because Whalen fails to teach each and every element of claim 3. Whalen is directed to novel methods for embolizing blood vessels which are particularly suited for treating aneurysms, AVM's and high flow fistulas (para. 0027). Thus, there is no teaching in Whalen of "wherein said localized region includes cancerous, engorged, inflamed or infected tissue." As such, even if claim 1 weren't patentable over Whalen, claim 3 is patentable over Whalen.

Claim 14

Claim 14 is patentable over Whalen because Whalen fails to teach each and every element of claim 14. While Whalen describes heating of the embolizing composition, the reference is completely silent as to how the thermal energy is applied. Accordingly, there is no teaching in Whalen of "wherein said energy is emitted by electrical contact." As such, even if claim 1 weren't patentable over Whalen, claim 14 is patentable over Whalen.

Claim 18

Claim 18 is patentable over Whalen because Whalen fails to teach each and every element of claim 18. Whalen is directed to methods for *embolizing* blood

vessels. The process of embolization involves obstructing the blood vessel by placing a material mass therein. There is no teaching or suggestion whatsoever in Whalen of "wherein said treatment includes shrinkage of said lumen or said sphincter to a selected dimension." As such, even if claim 1 weren't patentable over Whalen, claim 18 is patentable over Whalen.

Remaining Dependent Claims

Even without considering any individual merits of the remaining dependent claims, these claims are distinguished from Whalen because they depend from independent claims that are distinguished as discussed above. *Cf.* If an independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious. *Fine*, 837 F.2d at 1071. MPEP 2143.03.

3. Claims 1-3, 6, 8, 14, 18-19, 25-29, 32-3 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,994,069 ("Richart"). The current rejection is defective because the applied reference does not teach the features of the claims, as required by law. Claim 1 is patentable over Richart because Richart fails to teach the combination:

A method for treating a dilatation of a body, including the steps of:

inserting a catheter into a localized region of said body;

exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region;

allowing said substance to perfuse into a tissue of said localized region;

emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance; and

contracting said dilatation;

whereby at least some tissue in said localized region is treated.

Claim 1 is patentable over Richart because Richart fails to teach "exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region . . ." as arranged in claim 1 and in as complete detail as in claim 1. Richart describes an apparatus for occluding a blood vessel by placement of a wire coil in the blood vessel. While Richart does describe, at Col. 9, line 23 to line 36 back filling the wire coil with a collagen bolus, and injection of drugs into the collagen bolus, these treatments are described only as optional treatments to the treatment with the wire coil. The primary focus of Richart is the treatment based on the wire coil. The use of the collagen bolus and the drug therapy is described only as an embellishment to the wire coil. The wire coil is an essential component of Richart's invention. Because the collagen bolus and the use of drugs are not taught as separate treatments in their own right, but require the prior placement of the wire coil, Richart fails to describe "exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region . . ." as arranged in claim 1 and in as complete detail as in claim 1.

Claim 1 is further patentable over Richart because Richart fails to teach "allowing said substance to perfuse into a tissue of said localized region . . ." as arranged in claim 1 and in as complete detail as in claim 1. As above, any use of fluid is strictly an embellishment to Richart's basic invention. The prior use of the wire coil is a necessary condition to any use of fluids. Because the collagen bolus and the use of drugs are not taught as separate treatments in their own right, but require the prior placement of the wire coil, Richart fails to describe "allowing said substance to perfuse into a tissue of said localized region . . ." as arranged in claim 1 and in as complete detail as in claim 1.

Claim 1 is further patentable over Richart because Richart fails to teach "emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance . . ." There is absolutely no such teaching in Richart. Richart does teach at Col. 9, line 33 to line 34 that the occlusion coil

can be used to potentiate hyperthermic treatment. However, beyond this, Richart is completely silent as to how the thermal energy for the hyperthermic treatment is to be applied. Furthermore, the object of the hyperthermia appears to be heating of the tissue rather than heating of the substance. Thus, Claim 1 is patentable over Richart because Richart fails to teach "emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance . . . ."

Claim 1 is further patentable over Richart because Richart fails to teach "contracting said dilatation . . . ." As shown in Figs. 8-10 of Richart, Richart teaches the use of wire coils to *occlude* small blood vessels. Those having an ordinary level of skill in the art will understand the term "occlude" to mean "obstruct." The Examiner points to no teaching or suggestion in Richart that the wire coil is to be used to contract a dilatation such as an aneurysm. As such, Claim 1 is patentable over Richart because Richart fails to teach "contracting said dilatation . . . ."

The Examiner has failed to point to any specific teachings from Whalen that anticipate the elements of claim 1. Accordingly, she has failed to establish *prima facie* anticipation. On these facts alone, there is no anticipation of claim 1 by Whalen. Additionally, because Whalen fails to teach each and every element of claim 1, as required by law, there is no anticipation of claim 1 by Whalen. Accordingly, claim 1 is patentable over Whalen.

Claim 8

Claim 8 is patentable over Richart because Richart fails to describe "wherein said exuded substance includes a saline solution." Beyond backfilling the coil with a collagen bolus and placement of drugs within the collagen bolus, there is no description in Richart of "wherein said exuded substance includes a saline solution." Therefore, even if claim 1 were not patentable over Richart, claim 8 is patentable in its own right.

Claim 14

Claim 14 is patentable over Richart because Richart fails to describe "wherein said energy is emitted by electrical contact." Although Richart makes brief mention of hyperthermia, there is no mention of how or in what form the thermal energy is to be supplied. Because Richart fails to teach "wherein said energy is emitted by electrical contact . . . ," even if claim 1 were not patentable over Richart, claim 14 would be patentable over Richart.

Claim 15

Claim 15 is patentable over Richart because Richart fails to describe "wherein said emitted energy includes RF (monopolar or bipolar), microwave or laser." There is no mention in Richart whatsoever of any form of energy. Because Richart fails to teach ""wherein said emitted energy includes RF (monopolar or bipolar), microwave or laser . . . ," even if claim 1 were not patentable over Richart, claim 15 would be patentable over Richart.

Claim 18

Claim 15 is patentable over Richart because Richart fails to describe "wherein said treatment includes shrinkage of said lumen or said sphincter to a selected dimension." The sole treatment described by Richart is occlusion of small blood vessels using an occlusive coil. Certain embellishments to this basic treatment are also described. Because Richart fails to teach "wherein said treatment includes shrinkage of said lumen or said sphincter to a selected dimension . . . ," even if claim 1 were not patentable over Richart, claim 18 would be patentable over Richart.

Remaining Dependent Claims

Even without considering any individual merits of the remaining dependent claims, these claims are distinguished from Richart because they depend from

independent claims that are distinguished as discussed above. *Cf.* If an independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious. *Fine*, 837 F.2d at 1071. MPEP 2143.03.

4. Claims 1-3, 6, 8, 14, 18-19, 25-29, and 32-3 stand rejected under 35 USC § 102(e) as being anticipated by U.S. Patent Application Pub. No. US2002/0156531 ("Felt"). The current rejection is defective because the applied reference does not teach the features of the claims, as required by law.

Claim 1

Claim 1 is patentable over Felt because Felt fails to teach the combination:

A method for treating a dilatation of a body, including the steps of:

inserting a catheter into a localized region of said body;

exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region;

allowing said substance to perfuse into a tissue of said localized region;

emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance; and

contracting said dilatation;

whereby at least some tissue in said localized region is treated.

At the outset, claim 1 is patentable over Felt because Felt does not describe a method for treating a dilatation of a body. Felt is directed to methods and apparatus for treating bony and cartilaginous tissue (para. 0002). It is well known that dilatations are problems of soft tissue. The Examiner points to nothing in Felt that generally describes treatment of soft tissue or particularly describes treatment of dilatations.

Claim 1 is further patentable over Felt because Felt fails to teach:

"emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance . . . ."

The Examiner relies on para. 0310 as teaching "emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance . . . ." However, para. 0310 describes use of a heated probe to sculpt Felt's composite material. All other steps of the procedure are first completed: "The joint will then be irrigated and the instruments removed from the portals . . ." (para 0306). One having an ordinary level of skill will understand the "portals" to be the incisions through which instruments are inserted. Thus, after the biomaterial has been delivered to the joint through a catheter, the catheter is removed and the biomaterial allowed to cure.

"In yet another step of the present invention, the cured, retained biomaterial is contoured to achieve a desired conformation approximating that of natural tissue . . ." (para. 0309).

"The preferred composite is heat moldable, allowing for sculpting with a probe that can be introduced through an arthroscopic portal. . . "(para. 0310). Thus, Felt fails to teach "emitting <u>from said catheter</u> energy of a frequency and in an amount effective to cause a temperature change in said substance . . . ." In Felt, the catheter used to deliver the substance is removed, the substance is allowed to cure, and in a completely separate operation, the substance is contoured by inserting a separate instrument, a heated probe, through an arthroscopic portal.

Felt also teaches application of ultraviolet energy: "Preferred biomaterials are curable by application of ultraviolet light . . . "(para 0305). However, one having an ordinary level of skill would understand that UV light is applied to induce cross-linking, not to heat the biomaterial. Furthermore, there is no teaching or suggestion that the same catheter used to deliver the biomaterial is used to

deliver the UV energy. Accordingly, there is no teaching in Felt of "emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance . . . ."

Claim 1 is further patentable over Felt because Felt fails to teach:

"contracting said dilatation;

whereby at least some tissue in said localized region is treated."

There is no teaching in Felt of contracting a dilatation, which is a disturbance particular to soft tissue. In fact, Felt is overwhelmingly directed to repair of bony and cartilaginous tissue. While Felt appears to propose use of the described device in the manner of an angioplasty catheter to dilate stenotic lesions in blood vessels (para. 0290), there is no mention whatsoever of contracting dilatations. Furthermore, the treatment of stenotic lesions merely mentioned and is not described in sufficient detail to enable one having an ordinary level of skill in the relevant art

The Examiner has failed to point to any specific teachings from Felt that anticipate

"contracting said dilatation;

whereby at least some tissue in said localized region is treated."

Accordingly, she has failed to establish *prima facie* anticipation. On these facts alone, there is no anticipation of claim 1 by Felt. Additionally, because Felt fails to teach each and every element of claim 1, as required by law, there is no anticipation of claim 1 by Felt. Accordingly, claim 1 is patentable over Felt.

Applicant respectfully notes that the Examiner declined to respond to Applicant's argument concerning the element "contracting said dilatation; whereby at least some tissue in said localized region is treated." It is important, however, for an

examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply. MPEP § 706.02(j). In this respect, the Office Action is defective.

Claim 3

Claim 3 is patentable over Felt because there is no mention whatsoever in Felt of "treating cancerous, engorged, inflamed or infected tissue." Thus, even if claim 1 were not patentable over Felt, Claim 3 is patentable over Felt.

Claim 5

Claim 5, is patentable over Felt because there is no mention whatsoever in Felt of treating a cyst, tumor or wart tissue. Thus, even if claim 1 were not patentable over Felt, Claim 5 is patentable over Felt.

Claim 8

Claim 8 is patentable over Felt because there is no mention whatsoever in Felt that the substance includes a saline solution. Thus, even if claim 1 were not patentable over Felt, Claim 8 is patentable over Felt.

Claims 18 and 19

Claims 18 and 19 are patentable over Felt because there is no mention whatsoever in Felt of shrinkage of a lumen or sphincter. Thus, even if claim 1 were not patentable over Felt, Claims 18 and 19 are patentable over Felt.

Claim 25

Claim 25 is allowable over Felt because there is no mention whatsoever in Felt of avoiding local centers. Thus, even if claim 1 were not patentable over Felt, Claims 18 and 19 are patentable over Felt.

Claim 28

Claim 28 is patentable over Felt because there is no mention whatsoever in Felt of a space-filling balloon having a lumen through it. Thus, even if claim 1 were not patentable over Felt, Claims 28 is patentable over Felt.

Claim 36

Claim 36 is patentable over Felt because there is no mention whatsoever in Felt of a porous balloon, a microporous balloon, or a balloon with a porous or a microporous membrane. Thus, even if claim 1 were not patentable over Felt, Claim 36 is patentable over Felt.

Remaining Dependent Claims

Even without considering any individual merits of the remaining dependent claims, these claims are distinguished from Felt because they depend from independent claims that are distinguished as discussed above. *Cf.* If an Independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious. *Fine*, 837 F.2d at 1071. MPEP 2143.03.

In the response of November 18, 2004, Applicant extensively discussed the patentable merits of the dependent claims. Applicant respectfully notes that the Examiner declined to respond to Applicant's arguments concerning the dependent claims, in disregard of the directive of MPEP § 706.02(j). In this respect, the Office Action is defective.

35 U.S.C § 103(a): Claims 20, 23-24, 30-31

1. Claims 20, 23-24 and 30-31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Whalen in view of Guglielmi. As discussed above, Whalen fails to teach the combination described in Claim 1.

Claim 20

Claim 20 is patentable over the combination of Whalen and Guglielmi because the combination fails to teach "shrinkage of said engorged or inflamed tissue by removal of lipids or water." It has already been established that Whalen fails to teach shrinkage of tissue. While Guglielmi teaches shrinkage of tissue (Col. 4, line 26 to line 32), shrinkage occurs by application of RF energy to the tissue. Thus, the combination fails to teach all elements of Claim 20.

Claim 20 is further patentable over Whalen and Guglielmi because the Examiner has failed to explain why a practitioner of ordinary skill would be motivated to make the combination in order to derive the subject matter of claim 20. Thus, claim 20 is patentable over the combination of Whalen and Guglielmi because the rejection is defective.

Claim 23

Claim 23 is patentable over the combination of Whalen and Guglielmi because the combination fails to teach "destruction of a damaged or a diseased tissue." It has already been established that Whalen fails to teach destruction of damaged tissue. As established above, Guglielmi teaches shrinkage of tissue through application of RF energy. Thus, the combination fails to teach all elements of Claim 23.

Claim 23 is further patentable over Whalen and Guglielmi because the Examiner has failed to explain why a practitioner of ordinary skill would be motivated to

make the combination in order to derive the subject matter of claim 23. Thus, claim 23 is patentable over the combination of Whalen and Guglielmi because the rejection is defective.

Claim 24

Claim 24 is patentable over the combination of Whalen and Guglielmi because the combination fails to teach "promotion of epithelial growth." The Examiner admits that Whalen fails to teach promotion of epithelial growth. The Examiner takes the position that Guglielmi teaches "promotion of epithelial growth;" however she offers no evidence for her position, failing to point to a specific teaching from Gugielmi. In the response of November 18, 2004, Applicant extensively discussed Guglielmi and its failure to teach "promotion of epithelial growth." Applicant respectfully notes that the Examiner declined to respond to Applicant's argument, in disregard of the directive of MPEP § 706.02(j). On this ground alone, the rejection of claim 24 under 35 U.S.C. § 103(a) is improper. Additionally, however, Guglielmi fails to teach "promotion of epithelial growth." As a matter of fact, Guglielmi teaches away from "promotion of epithelial growth." At col. 9, line 4 to line to line 6, Guglielmi states that the "cage 20 freely collapses in response to the shrinkage of the adjacent vessel 74 without causing any tissue damage." Thus, because Guglielmi purports to achieve its result without injuring the tissue, there would be no reason to provide any affirmative means of promoting epithelial growth. Accordingly, one of ordinary skill would not be motivated to combine the teachings of Whalen and Guglielmi to derive the claimed invention. Thus, claim 24 is patentable over the combination because the combination fails to teach "promotion of epithelial growth." Claim 24 is further patentable over the combination because one of ordinary skill would not be motivated to make the combination.

Claims 30-31:

Even without considering any individual merits of claims 30-31, these claims are distinguished from the combination because they depend from independent claims that are distinguished as discussed above. If an independent claim is nonobvious under 35 USC 103, then any claim depending therefrom is nonobvious. *Fine*, 837 F.2d at 1071. MPEP 2143.03.

2. Claims 20, 23-24 and 30-31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lesh in view of Guglielmi. As discussed above, Lesh fails to teach the combination described in Claim 1.

Claims 20 and 23:

Claims 20 and 23 are patentable over Whalen and Guglielmi because the Examiner has failed to explain why a practitioner of ordinary skill would be motivated to make the combination in order to derive the subject matter of claim 23. Thus, claims 20 and 23 are patentable over the combination of Whalen and Guglielmi because the rejection is defective.

Claims 20 and 23 are further patentable over Whalen and Guglielmi due to their dependency from a patentable claim.

Claim 24

The above discussion of claim 24 with respect to Whalen and Guglielmi is applicable to the combination of Lesh and Guglielmi. The Examiner admits that Lesh does not teach "promotion of epithelial growth." In fact, Lesh describes destruction of tissue. As above, Gulgielmi fails to teach promotion of epithelial growth. Accordingly, claim 24 is patentable over the combination of Lesh and Guglielmi because the combination fails to teach "promotion of epithelial growth."

Claim 24 is further allowable in view of the impropriety of the Examiner's failure to respond to Applicant's discussion of the patentable merits of claim 24 in the response of November 18, 2004.

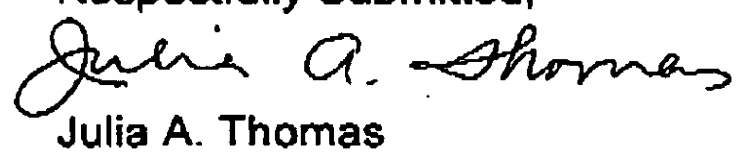
Claims 30-31.

As above, claims 30-31 are patentable over the combination of Lesh and Guglielmi in view of the dependency from patentable claim.

CONCLUSION

For the foregoing reasons, the claims in the present application are patentably distinguished over the cited references. Accordingly, all claims should be allowed without delay. Should the Examiner have any questions regarding the Application, he is urged to contact Applicant's attorney at the telephone number given below.

Respectfully Submitted,



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